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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,662	03/23/2007	Manohar Ratnam	05096	2188
7590 12/10/2009 Patrick P. Pacella Emch Schaffer Schaub & Porcello Co. PO Box 916 Toledo, OH 43697-0916				
EXAMINER				
HOLLERAN, ANNE L				
ART UNIT		PAPER NUMBER		
1643				
MAIL DATE		DELIVERY MODE		
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/549,662

**Applicant(s)**

RATNAM, MANO HAR

**Examiner**

ANNE L. HOLLERAN

**Art Unit**

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6 and 8-64 is/are pending in the application.
- 4a) Of the above claim(s) 8, 18-23, 28-33, 38-43, 48-53 and 58-64 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 9-17, 24-27, 34-37, 44-47 and 54-57 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The amendment filed 7/24/2009 is acknowledged. Claims 1-6, and 8-64 are pending.

Claims 18-23, 28-33, 38-43, 48-53, and 58-64, drawn to non-elected inventions, are withdrawn from consideration. Claim 8, dependent from a canceled claim, is withdrawn from consideration.

Claims 1-6, 9-17, 24-27, 34-37, 44-47 and 54-57 are examined on the merits.

#### ***Claim Objections/Rejections Withdrawn:***

##### ***Claim Objections***

The objection to claims 10 and 11 under 37 CFR 1.75(c) as being in improper form is withdrawn in view of the amendment to the claims.

The objection to claim 8 because of informalities is withdrawn in view of the amendment to the claims.

The objections to claim 9 are withdrawn in view of the amendments to claim 9.

The objection to claim 44 is withdrawn in view of the amendment to claim 44.

#### ***Claim Rejections Maintained and New Grounds of Rejection:***

##### ***Claim Objections***

Claim 8 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the

claim(s) in independent form. Claim 8 is dependent on a canceled claim. Claim 8 is withdrawn from consideration.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 3 and 5 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained for the reasons of record.

Claim 3 has been amended to have the phase "further comprising the step of performing a diagnostic assay using samples of said body fluid." The addition of this phrase does not obviate the rejection of record because the phrase "step of performing" does not apprise one of the reagents used, the analyte or analytes measured, or of what condition is to be diagnosed.

The amendment to claim 5 renders claim 5 indefinite because of the phrase "wherein the treating uses". The rejection of claim 5 also maintained for the reasons of record because claim 5 recites targeting folate receptor alpha, whereas claim 1 encompasses inducing folate receptor alpha.

Claims 1-6, 9-17, 24-27, 34-37, 44-47, and 54-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained for the reasons of record.

Claim 1 is indefinite because it recites the administration of at least one folate receptor alpha inducer, the at least one folate receptor alpha inducer comprising at least one steroid

receptor agent, and also recites that the folate receptor alpha inducer comprises at least one or more agonist or antagonist agent of at least one steroid receptor. Therefore, the scope of the claims is in question because the folate receptor alpha inducer is defined first as a steroid receptor agent and then as a agonist or antagonist agent of at least one steroid receptor.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 6, 12-16, 24-26, 34-36, 44-46 and 54-56 remain rejected under 35 U.S.C. 102(b) as being anticipated by Taylor (Taylor, C.W., et al. Breast Cancer Research and Treatment, 42: 7-14, 1997) as evidenced by Kelley (Kelley, K.M.M. et al. Cancer Research, 63: 2820-2828, 2003, June).

Applicants' arguments have been carefully considered, but fail to persuade. Applicants state that nowhere do the cited references disclose at least one or more agonist or antagonist agent of at least one steroid receptor. This does not appear to be correct, because Taylor teaches the administration of a combination of cyclophosphamide, vincristine, Adriamycin and dexamethasone (CVAD). Dexamethasone is steroid receptor agonist. Therefore, the rejection is maintained for the reasons of record.

Claims 1-3, 6, 12-16, 24-26, 34-36, 44-46 and 54-56 remain rejected under 35 U.S.C. 102(b) as being anticipated by Tamargo (Tamargo, R.J., et al. J. Neurosurg. 74(6): 956-961, 1991; abstract only) as evidenced by Kelley (Kelley, K.M.M. et al. Cancer Research, 63: 2820-2828, 2003, June).

The claims are drawn to methods comprising one step of administering at least one folate receptor alpha inducer, or of using at least one folate receptor alpha inducer, wherein the folate receptor alpha inducer is a steroid receptor agent. The elected species is a glucocorticoid receptor agent. The specification discloses that dexamethasone is a glucocorticoid receptor agent that induces folate receptor alpha. Kelley teaches that brain tumors expresses folate receptor alpha (see page 2820, left column). Claim 3 adds the active step of performing a diagnostic assay using samples of body fluids. However, there is no indication of what the diagnostic assay measures.

Tamargo teaches a method of administering a combination of cyclophosphamide, vincristine, Adriamycin and dexamethasone (CVAD) to Fischer 344 rats implanted with a 9L gliosarcoma of the brain. Tamargo teaches a diagnostic test using plasma to test for concentrations of dexamethasone. Therefore, Tamargo teaches a method that is the same as that claimed.

### ***Conclusion***

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on (571) 272-0832. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official

Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Anne L. Holleran  
Patent Examiner

December 5, 2009

/Alana M. Harris, Ph.D./

Primary Examiner, Art Unit 1643